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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,021	09/21/2000	Mary E. Brunkow	240083.508D2	1599

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EXAMINER

NOLAN, PATRICK J

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/668,021

Applicant(s)
Brunkow et al.

Examiner
Patrick J. Nolan

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 21, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 94-106 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 104 is/are allowed.
- 6) ☒ Claim(s) 94-103, 105, and 106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

Part III DETAILED ACTION

1. This application is a divisional of 09/449,218. Applicant is requested to update the status of the parent case on the first page of the specification.

2. Claims 94-106 are pending.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-21-03 has been entered.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 94-100, 102-103 and 105 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody to SEQ ID NOS 2, 6, 10, 12, 14 and 16, does not reasonably provide enablement for an antibody to a protein encoded by a polynucleotide that hybridizes to SEQ ID NO. 1, 5, 9, 11, 13 and 15 or a polypeptide encoded by a polynucleotide having 90% identity with a full length sequence selected from SEQ ID NOS 1, 5, 9, 11, 13 and 15.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

The use of Applicant's claimed antibodies is predicated on the ability of the antibody to bind TGF-beta binding protein. The scope of the rejected claims allows for amino acid substitutions in polypeptide by which the claimed antibody binds to. Applicant's specification has no working examples no specific guidance as to which amino acid sequences can be changed while maintaining the ability of the resulting antibody to bind TGF-beta binding protein. The state of the art, Colman et al. (U), teaches that single amino acid changes in antigen can abolish the antibody-antigen interaction entirely, providing an effective mechanism for antigenic variation (page 33, in particular). Therefore since applicant's claims read on changing the TGF-beta binding protein by

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creating homologous sequences, it is unpredictable whether said protein will bind to the original TGF-beta binding protein.

Since, Applicant has provided no working examples, and the state of the art as taught by Colman et al., teaches that single amino acid changes create unique and distinct antibodies which usually won't bind the original peptide, prior to its change, the practice of Applicant's invention would require an undue amount of experimentation for one of skill in the art to practice.

6. Claim 106 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no support in their originally filed claims or specification for an antibody that specifically binds to a polypeptide encoded by polynucleotide that is either 90% identical to SEQ ID NOS 1, 5, 9, 11, 13, 15 or hybridizes under stringent conditions to SEQ ID NOS 1, 5, 9, 11, 13, 15, and where said antibody also binds to naturally occurring BMP-5 or BMP-6.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 101 is rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,453,492, of record.

Claim 101 is not limited to the sequences but only to the named protein, TGF-beta binding protein. The '494 patent teaches methods of making monoclonal antibodies to TGF-beta binding protein.

The prior art teachings anticipate the claimed invention.

7. Claim 106 is objected to for misspelling morphogenic in line 2.

8. Claim 104 as presently recited is allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Tuesday through Friday from 9:30 am to 4:30 pm.

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10. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
April 5, 2003